

## **REMARKS**

### **FORMAL MATTERS:**

Claims 40-52, 91 and 93-94 are pending after entry of the amendments set forth herein.

Claim 95 is canceled without prejudice.

Claims 40 and 93 are amended. Support for these amendments is found in the claims as originally filed and throughout the specification at, for example, page 15, lines 7-20

No new matter is added.

### **REJECTIONS UNDER §112, ¶2**

Claims 93 and 95 are rejected under 35 U.S.C §112, second paragraph, as being indefinite for recitation of a “subsystem” in claim 93 and “door” in claim 95. Claim 93 has been amended to remove the objectionable language and claim 95 has been canceled. Therefore, this rejection may be withdrawn.

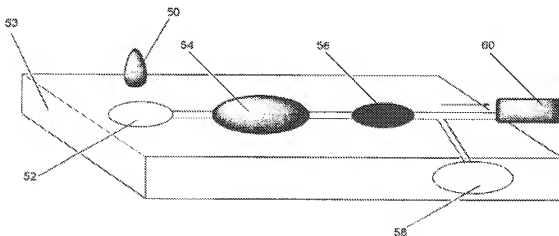
### **REJECTIONS UNDER §103(A)**

Claims 40-52, 91 and 93-94 are rejected under 35 U.S.C. §103(a) as being unpatentable over Law in view of Ullman and Zin. In view of the amendments to the claims and the remarks made herein, this rejection may be withdrawn.

A determination of obviousness is informed by an analysis of several factors: (1) the scope and content of the prior art; (2) the differences between the claimed invention and prior art; (3) the level ordinary skill in the art; and (4) any relevant secondary considerations (*Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)).

“Subsumed within the Graham factors is a subsidiary requirement articulated by this court that where, as here, all claim limitations are found in a number of prior art references, the burden falls on the challenger of the patent to show by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007) citing *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006) (emphasis added).

Law is cited for teaching a flow through cell for detecting glycated hemoglobin from a blood sample. Law teaches applying a blood sample to a sample well, lysing the blood sample with a lysing agent, transporting the mixture to a capture zone, binding glycated proteins, such as glycated hemoglobin with a capture agent, adding a developing solution that reacts with glycated hemoglobin, transporting the dye to a detection zone and detecting the change in the dye. Therefore, **Law teaches detection of a dye at a location different than where the glycated protein is captured.** As describe in Example 5 of Law and shown in Fig. 8 reproduced below, the glycated proteins are captured at position 54 and the dye is then added at position 52 and detected at position 56.



**Fig. 8**

In contrast, the present invention is directed at detecting the captured analyte rather than a dye that is reacted with the captured analyte. In the spirit of expediting prosecution and without conceding to the correctness of the rejection, claim 40 has been amended to clarify that **a level of the analyte captured at the second location is detected.**

The Office Action also cites Zin and Ullman for their alleged disclosures of devices with a membrane having an elution area, a sample addition area, a lysing area and a capture area. The Office Action further concludes that it would have been obvious to one of ordinary skill in the art at the time

the invention was made to modify the device taught by Ullman to detect glycosylated hemoglobin as taught by Law.

However, the Applicants respectfully disagree. As noted above, Law teaches capturing of all glycosylated proteins at the capture zone. In order to distinguish between different glycosylated proteins, such as glycosylated albumin, Law teaches use of a dye that is catalyzed by the glycosylated hemoglobin and then detection of the dye (see Law, Column 4, lines 19-24).

Therefore, the system of Ullman or Zin cannot be modified based on Law to detect a specific analyte, such as glycosylated hemoglobin, present at a capture site due to the non-specific nature of the capture zone of the system of Law. In particular, Law states that the capturing is achieved by using an immobilized boronic acid derivative that binds to all glycosylated proteins, including glycosylated albumin and glycosylated hemoglobin (Column 4, lines 5-24). Due to the non-specific nature of the capture agent, Law requires the use of a separate dye to detect the glycosylated hemoglobin. In fact, Law states that the dye used in the system provides “a unique advantage” for the disclosed system because “other blood glycosylated proteins that bind to the solid support, e.g., glycosylated albumin,” will not have to be separated out using antibody or other means” (Column 4, lines 19-24, emphasis added).

Therefore, modification of Ullman or Zin with Law, as suggested by the Office Action, would result in immobilization of all glycosylated proteins. Moreover, without the separate detection zone and the use of the detection dye as disclosed in Law, one would not be able to differentiate between the different glycosylated proteins immobilized at the capture zone.

Therefore, since Law alone or in combination with Zin and Ullman fails to teach each and every element of the claims, the cited references cannot render the present claims obvious. As such, the Applicants respectfully request that this rejection be withdrawn.

**CONCLUSION**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number ADCI-010.

Respectfully submitted,  
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